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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/075,053      | 02/13/2002  | Robert C. Stevens    | RST 2 0011-3        | 8092             |

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Michael E. Hudzinski  
FAY, SHARPE, FAGAN, MINNICH & McKEE, LLP  
7th Floor  
1100 Superior Avenue  
Cleveland, OH 44114-2518

EXAMINER

MEHTA, BHISMA

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3767

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/075,053 | <b>Applicant(s)</b><br>STEVENS, ROBERT C. |  |
|                              | <b>Examiner</b><br>Bhisma Mehta      | <b>Art Unit</b><br>3767                   |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.  
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-24 and 26-65 is/are pending in the application.  
4a) Of the above claim(s) 12-23 and 29-40 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1,3-11,24,26-28 and 41-65 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 47 and 48 are objected to because of the following informalities: Claims 47 and 48 recite the limitation "the continuous coil reinforcement member" in line 2. There is insufficient antecedent basis for this limitation in the claims. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4, 5, 44, 45, 54, and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 4, 44, and 54, it is unclear on which outer coating, i.e. the first or the second outer coating, the marker band is disposed.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1, 3, 6-11, 24, 26-28, 41-43, 46-53, and 56-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Nita et al (U.S. Patent 5,951,539). Nita et al disclose a reinforced catheter having an elongate flexible tubular member (528) defining a lumen, a continuous coil reinforcement member (522) carried on the tubular member, a first flexible outer coating (546), and a second flexible outer coating (542). In lines 9-28 of column 9, Nita et al teach that the continuous coil reinforcement member extends from the proximal end of the catheter and terminates at the distal end of the catheter. In Figure 10, Nita et al show a first outer coating (546) which covers the coil reinforcement member and tubular member substantially entirely between the proximal end and the distal end of the catheter. A second outer coating (542) covers a first portion of the first outer coating between a transition area of the catheter and the proximal end of the catheter. A second portion of the first outer coating between the first transition area and the distal end of the catheter is uncovered by the second outer coating, thus defining a flexible distal tip. In lines 7-18 of column 16, Nita et al teach that the material of the second outer layer would be chosen such that additional stiffness would be provided to the proximal section of the catheter, thus the first coating is softer than the second coating. In lines 36-56 of column 14, Nita et al disclose the first outer coating at a distal section (246) of the catheter having a Shore hardness of about 40D and at a proximal section (240) of the catheter having a Shore hardness of about 70D. Thus, in the embodiment shown in Figure 10, when the first outer coating (546) has a Shore hardness of 40D, the material of the second outer coating (542) could be chosen to have a Shore hardness of 70D to provide additional stiffness in that proximal section as

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taught by Nita et al. The tubular member is formed of polytetrafluoroethylene (PTFE) (lines 34-39 of column 10) and the continuous coil reinforcement is a stainless steel wire and defines a helical pattern (lines 9-28 of column 9). In Figure 10, the distal end of the catheter is less than a thickness of the proximal end of the catheter. The first and second outer coatings may be made of a nylon or an urethane material (lines 19-35 of column 13). As to claim 24, the elongate flexible tubular member has a first end defining a lead end and a second end defining a trailing end and the continuous coil reinforcement member extends from the lead end to the trailing end. In Figure 14F, a continuous outer coating of a first material (572) covers the coil reinforcement member and the tubular member substantially entirely between the lead end and the trailing end. A continuous outer coating of a second material (590) covers the continuous outer coating of the first material (572) substantially entirely between the lead end and the trailing end. In line 65 of column 8 to line 7 of column 9, Nita et al teach that additional layers of polymeric material may be placed between the coil reinforcement member and the outer coating covering the reinforcement member. Additionally, in lines 16-18 of column 13, Nita et al teach that the polyethylene layer (which is the outermost layer or outer coating of the second material) may be left in place which is shown in Figure 14F. As to claim 26, Nita et al teach that the materials for the outer coatings may be chosen to have various values of Shore hardness, including the first material having a Shore hardness of 40D and the second material having a Shore hardness of 70D.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 4, 5, 44, 45, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nita et al in view of Follmer et al (U.S. Patent No. 5,728,065). Nita et al disclose the catheter substantially as claimed. Even though Nita et al teach (in lines 21-31 of column 18) that it is desirable to use a platinum radio-opaque or marker band adjacent the distal end of the catheter (506 in Figure 8, 534 in Figure 9), Nita et al are silent on the specifics of the marker being disposed on the outer coating. Follmer et al teach a marker band (124) disposed adjacent the distal end of the catheter on the outer coating in the same field of endeavor of reinforced catheters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the marker band of Nita et al on the outer coating as taught by Follmer et al as both Nita et al and Follmer et al teach that it is desirable to provide catheters with marker bands and Follmer et al teach that the marker bands can be placed on the outer coating of the catheter.

***Response to Arguments***

8. Applicant's arguments with respect to claims 1, 3-11, 24, 26-28, and 41-65 have been considered but are moot in view of the new ground(s) of rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
BM

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

